

July 15, 2008



Indiana Economic Development Corporation

Barbara McNutt  
Chief Counsel  
Indiana Professional Licensing Agency

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Dear Ms. McNutt:

Pursuant to IC 4-22-2-28, the Indiana Economic Development Corporation ("IEDC") has reviewed the economic impact analysis for small business associated with rule changes proposed by the Indiana Professional Licensing Agency ("IPLA") on behalf of the Indiana Board of Pharmacy ("Board") and contained in LSA Document 07-541. The proposed rule makes changes to 856 IAC 4 to establish standards for pharmacists administering immunizations for influenza under a physician's approved protocol as is permitted by IC 25-26-13-31.2. The change complies with a mandate from the Indiana General Assembly to adopt rules under IC 4-22-2 concerning qualifications, protocols, and record keeping for pharmacists to administer immunizations. Board records indicate that there are 1,400 pharmacies, 160 ambulatory health care facilities, 125 hospitals, 518 nursing and residential comprehensive care facilities, and 88 residential care facilities that are affected by the proposed rule. The board estimates that approximately 400 of the pharmacies affected by the proposed rule meet the definition of a small business under IC 4-22-2-28.

Potential costs occurring as result of the proposed rule include costs for training required for pharmacists to immunize under a protocol rather than prescription. The cost to an individual business would range from \$0 to \$215.00 per employed pharmacist. Importantly, immunization training is available through free on-line continuing education programs. In lieu of free on-line training, the Indiana Pharmacists Alliance provides training courses for \$215.00 per pharmacist. Board research suggests that pharmacies that choose to offer vaccinations under a protocol see a significant increase in vaccinations at their pharmacies. Thus, the expenses associated with the rule may be offset by the increase in business.

The rule also requires some additional record keeping and required reporting in limited instances. All pharmacies are already required to engage in record keeping related to drug dispensing and administration by both state and federal law and that record keeping is not impacted by the law. The only additional record keeping and reporting required in the event of an adverse event associated with the immunization. In the event of an adverse event, the pharmacist must report to the patient's physician and the physician that approved the protocol. The event must also be reported to the Vaccine Adverse Events Reporting System ("VAERS"). There is no cost to report to VAERS and the reporting can be done electronically.

The total cost for all affected businesses to comply with the rule ranges from zero dollars (if all 6,463 active pharmacists licensees with Indiana addresses elect to take the free online training) to \$1,389,545 (if all 6,463 active pharmacist licensees with Indiana addresses elect to take the \$215.00 course). Importantly, the training is only required for those pharmacies who choose to offer the immunizations through a physician's approved protocol rather than prescription, and training is available on-line at no cost.

The IEDC does not object to the economic impact to small businesses associated with the proposed rule. The training required by the rule is needed to ensure that pharmacists who immunize have the proper skill set to provide this service to patients, and these requirements are expressly required by statute.

If you have any questions about the comments contained herein please contact me at 232-8962 or [rasberry@iedc.in.gov](mailto:rasberry@iedc.in.gov).

Regards,

A handwritten signature in black ink, appearing to read "Ryan Asberry", with a long horizontal flourish extending to the right.

Ryan Asberry

Assistant Vice President